IV. 510(K) SUMMARY: CARESIDE® *TRIGLYCERIDE* SAFETY AND EFFECTIVENESS

I. Applicant Information

A.	Applicant Name	**CARESIDE, Inc.**
B.	Applicant/Manufacturer Address	6100 Bristol Parkway Culver City, CA 90230
C.	Telephone Number	310-338-6767
D.	Contact Person	Kenneth B. Asarch, Pharm.D., Ph.D.
E.	FAX Number	310-670-6986
F.	e-Mail Address	AsarchK@CARESIDE.com
G.	Date 510(k) Summary prepared	January 31, 2002

II. Device Information

A.	Device Name (Trade)	CARESIDE *Triglyceride*
B.	Device Name (Classification)	Triglyceride test system
C.	Device Classification	Clinical chemistry panel Triglyceride test system Regulation Number: 21 CFR 862.1705 Regulatory Class I Classification Number: 75CDT
D.	Special controls and performance standards	None applicable

III. Substantial Equivalence Claim

A. General equivalency claim

The ability to monitor analyte-specific biochemical reactions in dry film and other formats is widely recognized and has gained widespread acceptance for use in chemistry assays.

Triglyceride *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market, including triglyceride products which utilize lipase hydrolysis coupled to a glycerol kinase based reflectance detection system for glycerol.

B. Specific equivalency claim

The CARESIDE *Triglyceride* test is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Vitros slides for the quantitative measurement of triglycerides on the Vitros DT 60 II.

Name of Predicate Device:	Johnson and Johnson's (formerly Eastman Kodak, Inc.) Vitros TRIG Slides for Johnson and Johnson's Vitros DT 60 (formerly Eastman Kodak's DT 60 II).
Predicate Device 510K number:	K912844/A
Product Code:	75CDT

IV. Device Description

CARESIDE *Triglyceride* cartridges are used with the CARESIDE *Analyzer* to measure triglyceride concentration in anti-coagulated whole blood, plasma or serum specimens. The CARESIDE *Triglyceride* cartridge, a single use disposable *in vitro* diagnostic test cartridge, aids in specimen separation and delivers a measured volume of plasma or serum to a dry film to initiate the measurement of triglyceride concentration. The patented film cartridge contains all reagents necessary to measure triglyceride concentration.

A. Explanation of Device Function

Each CARESIDE *Triglyceride* cartridge consists of a triglyceride-specific multi-layer reagent film mounted in a plastic base with a hinged lid. The user introduces the anti-coagulated whole blood, serum, or plasma specimen into the cartridge Sample Well, closes the lid and inserts the cartridge into the CARESIDE *Analyzer*.

Once loaded, the CARESIDE *Analyzer* scans the cartridge barcode, brings the cartridge and the contained specimen to 37°C, and spins the cartridge to move the sample from the sample deposition well into the cartridge channels and chambers. As the cartridge continues to spin, the blood cells are separated from the plasma/serum and the cells accumulate in the separation well. Approximately 8.5 microliters of plasma (or serum, as applicable) remain in the metering passage. Any excess sample flows into an overflow well.

The plasma (or serum, as applicable) is automatically dispensed onto the multi-layer reagent film. The triglyceride-containing specimen is distributed uniformly by the spreading layer. The sample then passes through a reflection layer and into the reaction layer. Finally, the reaction mixture is pulled through the reaction layer by a suction layer where the NTB chromogen is converted into a purple formazan dye.

As the cartridge spins, a photodiode measures film reflectance of light emitted from a wavelength-specific light emitting diode (LED) at a fixed time. The instrument uses the reflectance measurements and the lot-specific standard curve to calculate triglyceride concentration.

Test Reaction Sequence:

$$\text{Triglycerides} \xrightarrow{LPL} \text{Glycerol} + \text{Fatty Acid}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{GK\ Mg^{++}} \text{G-3-P} + \text{ADP}$$

$$\text{G-3-P} + \text{NAD}^{+} \xrightarrow{G\text{-}3\text{-}PD} \text{DHAP} + \text{NADH}$$

$$\text{NTB} + \text{NADH} \xrightarrow{Diaphorase} \text{Formazan dye} + \text{NAD}^{+}$$

As the cartridges spin, photodiodes measure reflectance of light emitted by wavelength-specific light emitting diodes (LEDs) at a fixed time. The instrument uses the reflectance measurements and the lot-specific standard curve to calculate triglyceride concentration.

B. Test Summary

Triglycerides, consisting of fatty acids in ester linkages with glycerol, are the major form of fat found in the body. The primary function of triglyceride is to store energy.

Elevated triglycerides in patients reflect primary disorders of lipid metabolism or hyperlipoproteinemia secondary to known diseases including diabetes mellitus, nephrosis, biliary obstruction, pancreatitis and metabolic disorders associated with endocrine disturbances. Elevated levels of triglycerides has been identified as a risk factor related to atherosclerotic disease leading to coronary heart disease. Plasma levels of triglycerides can vary independently of lipoprotein levels; therefore evaluation of hyperlipidemias should include determinations of triglycerides.

V. Intended Use

A. Intended Use

The CARESIDE *Triglyceride* cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE *Analyzer* to quantitatively measure the concentration of triglycerides in anti-coagulated whole blood, plasma or serum.

B. Indications for Use

This product is indicated for use in the diagnosis and treatment of patients with primary or secondary hyperlipidemias. Hyperlipidemias may result from liver obstruction, diseases involving lipid metabolism, or various endocrine disorders. Triglyceride results are used together by the CARESIDE *Analyzer* with total cholesterol and HDL-cholesterol results to calculate LDL-cholesterol levels.

VI. Technological Characteristics

A. Similarities

	CARESIDE *Triglyceride*	**Vitros TRIG DT Slides**
Intended Use	Primarily to aid in the diagnosis and treatment of patients with primary or secondary hyperlipidemias.	Same
Indications	For *in vitro* diagnostic use.	For *in vitro* diagnostic use
Measurement	Quantitative	Same
Method Principle	Dry film based lipase hydrolysis. Dye quantitated by reflectance measurement after fixed time.	Same
Specimen dilution	Not required	Same
Materials	Lipoprotein lipase and coupling enzymes and co-factors	Lipoprotein lipase and coupling enzymes and co-factors (some same and some different)
Detector	Reflectance (570 nm)	Reflectance (555 nm)
Test time	Approx. 4 minutes warm-up (on-board) plus 6 minute test time.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Sample Type	Serum, plasma, whole blood [whole blood applied sample, plasma test sample]	Serum, plasma
Specimen volume	8.5 µl test volume (90 ± 10 µl applied volume)	10 µl
Calibration	Calibration information bar-coded on each cartridge. Calibration information may change with each lot.	Run Vitros DT II calibrators whenever a new slide lot is used or when necessary.
Quality Control	2 levels	Same
Reporting Units	mg/dL or mmol/L	Same
Reaction Temp.	37 °C	Same

B. Differences

	CARESIDE *Triglyceride*	**Vitros TRIG DT Slides**
Direct blood specimen	Yes, whole blood	No, requires separation of whole blood prior to sample application
Reportable range	25 to 500 mg/dL	15 to 400 mg/dL
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE *Triglyceride*	**Vitros TRIG DT Slides**
Detection limit	25 mg/dL	15 mg/dL
Reportable range	25 to 500 mg/dL	15 to 400 mg/dL
Accuracy	Mean recovery 99%	Not provided
Precision	Total CV, 146 mg/dL, 3.4%	Total CV, 189 mg/dL, 2.1%
Method comparison	CARESIDE= 0.98 (BM/Hitachi 902) + 2.92 mg/dL r= 0.99	
Linearity	Linearity by mixing and by dilution yielded slope and correlation coefficient within acceptable limits.	Not provided
Interference	No significant interference observed at tested concentration of interferent: Ascorbic acid, 10 mg/dL Bilirubin, 10 mg/dL Hemoglobin, 500 mg/dL	None stated
Specimen Types & Anticoagulants	No clinically significant difference between sodium heparinized whole blood, sodium heparin plasma, and EDTA plasma. Serum results are slightly higher.	No clinically significant difference between serum, heparin plasma, or EDTA plasma. Whole blood is unsuitable.

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE *Triglyceride* product is as safe, effective, and performs as well as or better than the legally marketed predicate device.

V. PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as the VP Quality Systems and Regulatory Affairs of CARESIDE, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Signature: Kenneth B. Asarch

Kenneth B. Asarch, Pharm.D, Ph.D.

Date: January 31, 2002

Premarket notification 510(k) Number: _____ (to be assigned.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kenneth B. Asarch, Ph.D.
VP Quality Systems and Regulatory Affairs
CARESIDE, Inc.
6100 Bristol Parkway
Culver City, CA 90230

APR 1 5 2002

Re: k020488
Trade/Device Name: CARESIDE Triglyceride
Regulation Number: 21 CFR 862.1705
Regulation Name: Triglyceride test system
Regulatory Class: Class I, reserved
Product Code: CDT
Dated: January 31, 2002
Received: February 13, 2002

Dear Dr. Asarch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VI. INDICATIONS FOR USE

510(k) Number:

Device Name: CARESIDE *Triglyceride*

Indications for use: For *in vitro* diagnostic use with the CARESIDE *Analyzer* to measure triglycerides in anti-coagulated whole blood, plasma or serum specimens. The CARESIDE *Triglyceride* test aids in the diagnosis and treatment of patients with primary or secondary hyperlipidemias (hyperlipidemias may result from liver obstruction, diseases involving lipid metabolism, or various endocrine disorders. Triglyceride results are used together by the CARESIDE *Analyzer* with total cholesterol and HDL-cholesterol results to calculate LDL-cholesterol levels).

(Division Sign-Off)
Division of Clinical Labora
510(k) Number K020488

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